

REMARKS

Applicants have amended claims 12 and 18 such that they recite "a method for treating obesity consisting of administering to a patient....".

Claims 12-13, 15-17, 18, 20 and 21 stand rejected under 35 U.S.C. 102(e) for purportedly being anticipated by Cheng et al. In view of the amendments to the claims and the following remarks, Applicants request that the Examiner reconsider and withdraw the rejection.

As amended the claims are limited to methods for treating obesity that consists of administering a pharmaceutical formulation that consists of an effective dosage of metformin and an effective dosage of PPAR α agonist and a pharmaceutical carrier. Cheng et al. do not teach compositions consisting of these components and thus does not anticipate the invention as claimed.

In view of the amendments to the claims and the foregoing remarks, Applicants request that the Examiner reconsider and withdraw the rejection of Claims 12-13, 15-17, 18, 20 and 21 under 35 U.S.C. 102(e).

Claims 12-17, 18, 20 and 21 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Lee et al. in view of Chaput et al. Claims 12-17, 18, 20 and 21 also stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Lee et al. in view of Piomelli et al. In view of the amendments to the claims and the following remarks, applicants request that the Examiner reconsider and withdraw the rejections.

As amended the claims are limited to methods for treating obesity that consists of administering a pharmaceutical formulation that consists of an effective dosage of metformin and an effective dosage of PPAR α agonist and a pharmaceutical carrier. On page 14, lines 1-4 Applicants disclose that comparing this di-therapy of metformin and fenofibrate to the monotherapy of metformin alone or fenofibrate alone demonstrates that the ditherapy produces

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an effect that is not a simple addition of the mono-therapies, but rather a synergy. Such a synergy could not be predicted based upon the art at the filing date of this invention.

In support of their application, Applicants have provided a Declaration of Jean-Louis Junien Under 37 CFR 1.132. Dr. Junien, an inventor of this application, states that the results in Table 3 demonstrate that the administration of fenofibrate and metformin significantly lowers the body weight gain in obese rats and that the difference is superior to the addition of the effects of the two compounds alone (page 1, paragraph 10). Dr. Junien also declares that the analyses set forth in Table 3 were carried out by using Dunnett's test and that this test is an appropriate statistical test to compare each of the different test groups with a control group (page 1, paragraph 11.) Dr. Junien states that a worker in the field of pharmacology would not be led to specifically combine metformin and fenofibrate (or fenofibric acid or a salt of fenofibric acid) in a formulation to treat obesity and could not expect that such a particular combination would have a significant effect on body weight reduction as depicted in Table 3 (page 2, first full paragraph). One of skill in the art based upon the cited references would not expect that the combination of just metformin and fenofibrate would produce a synergistic effect, i.e., one that is more than simply the addition of the effects of either alone. Thus the combination of Lee and Chaput or the combination of Lee and Piomelli does not render the present claims obvious.

In view of the amendments to the claims and the forgoing remarks, Applicants request that the Examiner reconsider and withdraw the rejection of claims 12-17, 18, 20 and 21 under 35 U.S.C. 103(a) for purportedly being unpatentable over Lee et al. in view of Chaput et al. and the rejection of claims 12-17, 18, 20 and 21 35 U.S.C. 103(a) for purportedly being unpatentable over Lee et al. in view of Piomelli et al.

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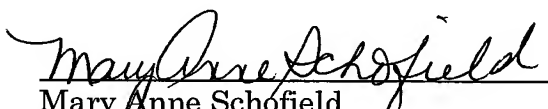
If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and

please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #102717.58257US).

Respectfully submitted,

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